



McKesson Pharmaceutical Controlled Substance Monitoring Program (CSMP)

DEA Discussion Document
July 31, 2008



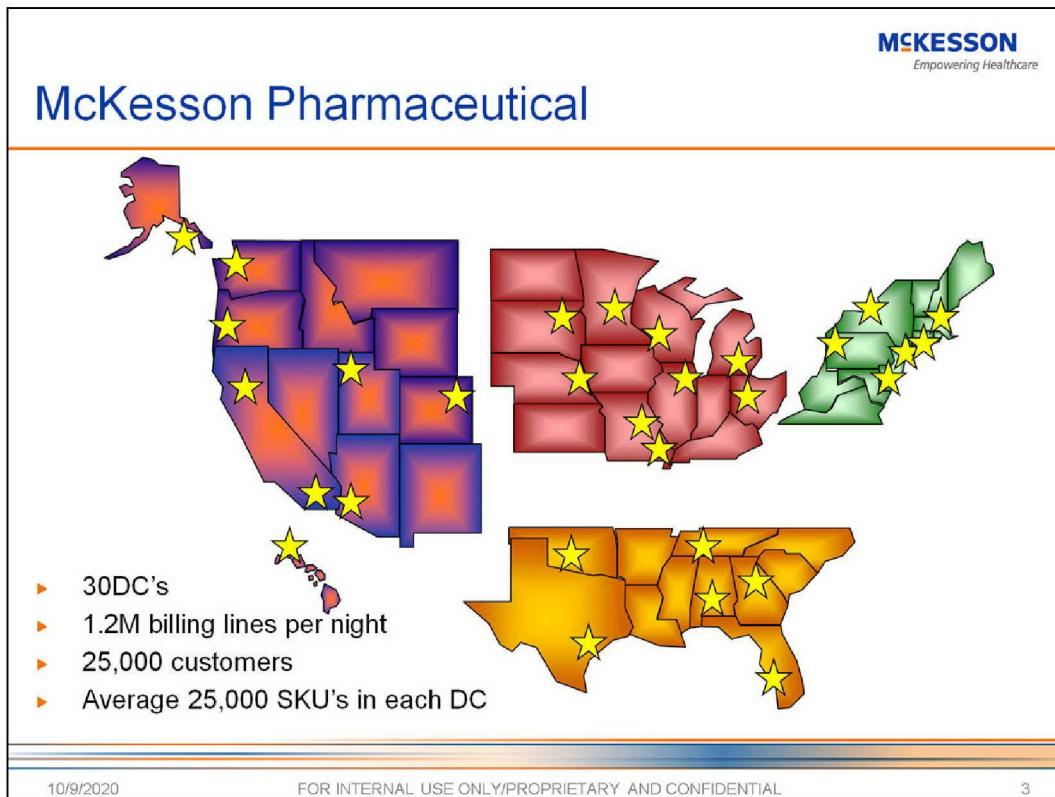
Topics of Discussion

- ▶ Overview of McKesson business
- ▶ Controlled Substance Monitoring Program
- ▶ SOP's and Training
- ▶ Conroe Suspension

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CSMP Components

- I. Know the Customer – Establish thresholds
- II. Monitor CS orders against thresholds
- III. Block orders that exceed thresholds
- IV. Review and escalation process
- V. Suspicious order/sales reporting
- VI. Analysis and reports

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CSMP Development History

April 2007

- ▶ Implemented Lifestyle Drug Monitoring Program
 - First use of dose units by base code
 - Track monthly sales
 - Review and document
 - Hydrocodone, Oxycodone, Alprazolam, Phentermine
- ▶ Created a three tier review process
 - Included customer visits and documentation
- ▶ Detected and reported suspicious pharmacies

September 2007

- ▶ DEA Meeting triggered new development – CSMP
- ▶ \$1.5M in development costs

April 2008

- ▶ Launched CSMP
- ▶ Customer communications

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I. Establish Customer Thresholds

- ▶ Established family codes
 - Default thresholds based on store volume
- ▶ Existing Customers
 - Analysis of 12 month purchase history
 - Set threshold if above family code default
 - Default if below
 - Conducting site visits to customers based on priority
 - Independents
 - Lifestyle Drugs
 - Dose units greater than 25K
 - Retail Chain – review with internal regulatory

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Establish Customer Thresholds Cont.

- ▶ New Customers
 - Questionnaire – purchase history/business model
 - Regulatory Approval
- ▶ Adjusting Thresholds
 - Requires documentation
 - Regulatory approval
- ▶ Threshold Database
 - 15,000+ family codes/threshold baseline
 - Each customer threshold maintained in the customer master

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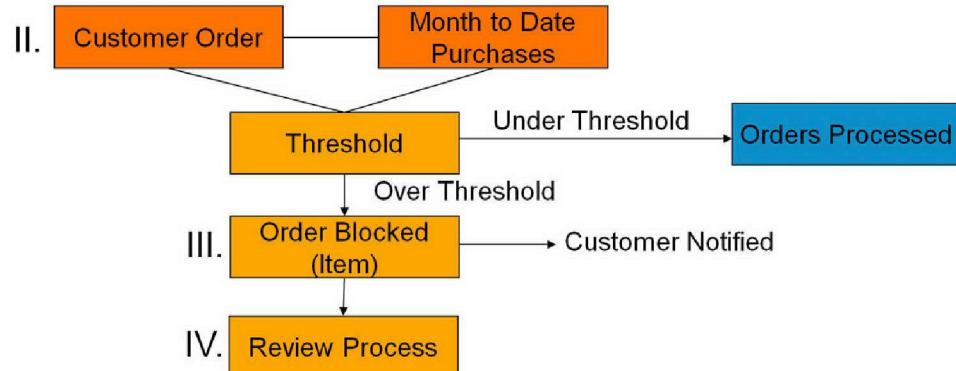
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II. Monitoring Controlled Substances

I. Customer Purchases Accumulated Monthly

- Dose units
- Base code



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III. Blocking Orders



- ▶ System Blocks Orders That Exceed Threshold
 - Specific to that base code
 - Specific to registrant
- ▶ No override
 - Requires change in threshold
 - Documented threshold change request required
- ▶ Customer Notification
 - Alert customer approaching threshold
 - Order entry systems alert customer
 - Invoice notifies customer
- ▶ Audit conducted
 - Since go live McKesson Internal Audit has conducted systems audit

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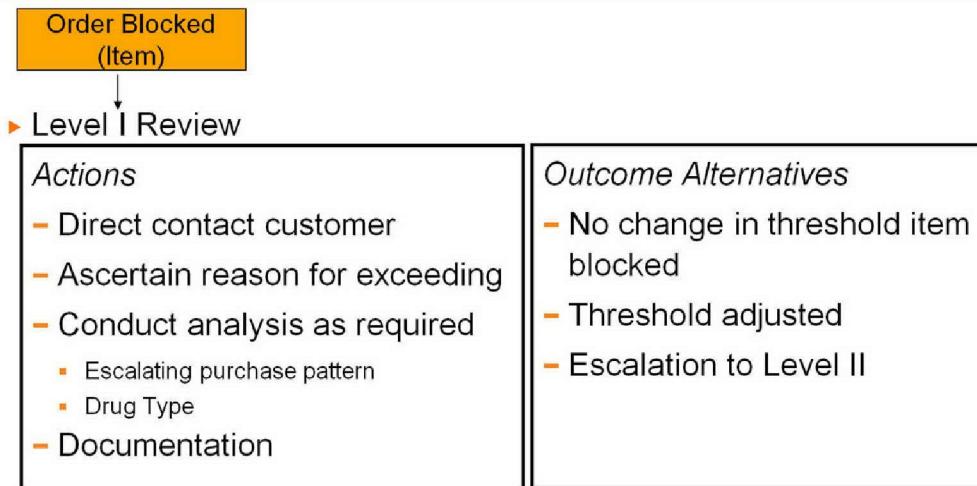
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IV. Review and Escalation

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IV. Review and Escalation Cont.

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Level II Review

Actions

- ▶ Conducted by Director of Regulatory Affairs
- ▶ Includes
 - Customer interview/site visit
 - Observations of DRA
 - Clientele
 - Customer traffic
 - Source of scripts
 - Local DEA input
 - Analysis of purchases
 - Increases

Outcome Alternatives

- Leave item blocked
- Adjust threshold
- Escalate to Level III

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IV. Review and Escalation Cont.

Level III Review

- ▶ Escalated to SVP of Distribution and Region SVP
- ▶ Any customer escalated to Level III all controlled substances purchases blocked
- ▶ Reported to DEA as suspicious
- ▶ Review with McKesson Legal
- ▶ Provide DEA with data and findings

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V. Suspicious Order/Sales Reporting

- ▶ McKesson is prepared to stop excessive purchases reporting to local field office
- ▶ Recent contact with DEA to determine format
 - Concern about format and process
- ▶ Need to create feedback process on those reported

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VI. Analysis and Reports

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- ▶ Developed tools for tracking and analysis
- ▶ Tracking tools
 - Threshold reports
 - E.g. – Customer approaching early in month – why?
 - Exceed threshold report
- ▶ Analysis
 - Lifestyle report
 - Generics purchase analysis
 - SAP sales report
 - Ad Hoc reporting
 - DEA/State BoP websites
 - Google Searches

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CSMP SOP's and Training



SOP's

- ▶ Detailed SOP (18 pages) for CSMP
 - SOP follows outline in this presentation
- ▶ Provides for:
 - Thresholds
 - Threshold Review
 - New Customer On Boarding
 - Due Diligence
 - Document Retention

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CSMP SOP's and Training Cont.



Training

- ▶ Field Operations Leadership
 - Two hours training in May – Legal/Regulatory trainers
 - Ongoing training via on site with Directors of Regulatory
- ▶ DC Warehouse Associates
 - Orientation for cage/vault
 - Developing detailed training program
- ▶ Customer Service
 - All customer service trained and supported by online protocol

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Where We Need Your Help

- ▶ Suspicious Order Reporting
 - Process and format
- ▶ Investigative Support
 - Mechanism to discuss customers of interest
 - Feed back that does not compromise investigation
 - Mutually identifying “script mills”
- ▶ Forum to discuss trends
 - E.g. Internet vs. Pain Clinic

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How We Can Help DEA

- ▶ Information
 - Systems data
 - Observations
- ▶ Trends
 - We see geographic differences
- ▶ Education
 - Provide insight into distributors processes
 - Drive industry awareness
 - Support pharmacist education

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Conroe Hydrocodone Sales

- ▶ Discovered July 8 we had made limited sales of cough and cold
- ▶ 70 transactions – 57 customers (53 Retail Chain)
 - Small purchases
 - Small quantities
- ▶ Error occurred in development of blocked item list – manual process
 - Items marked as manufacturer discontinued
 - Individual coding the list believed they would not be in Conroe

Actions

- ▶ Items now on blocked list
- ▶ Daily monitoring of new items – check against website
- ▶ All Hydrocodone and Alprazolam quarantined
 - Systemically
 - Physically
- ▶ All non – VA items marked as unsaleable
- ▶ Refresher training of associates

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